

July 6, 1954

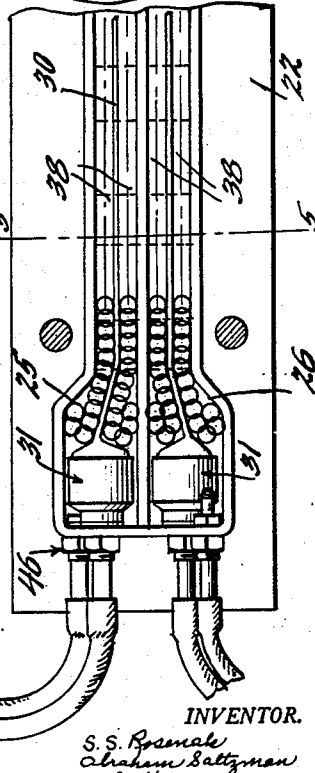
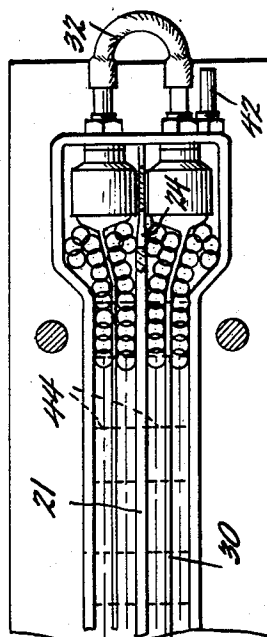
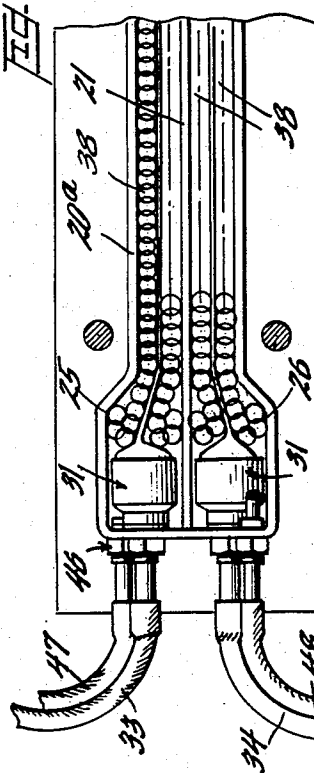
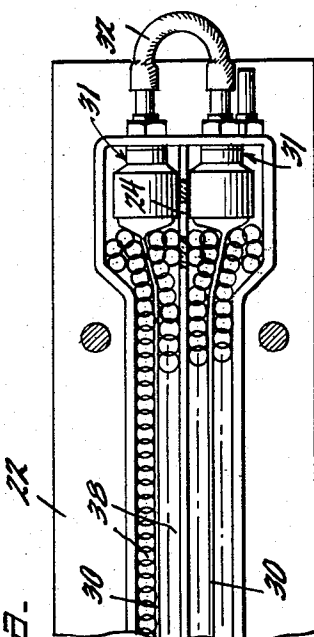
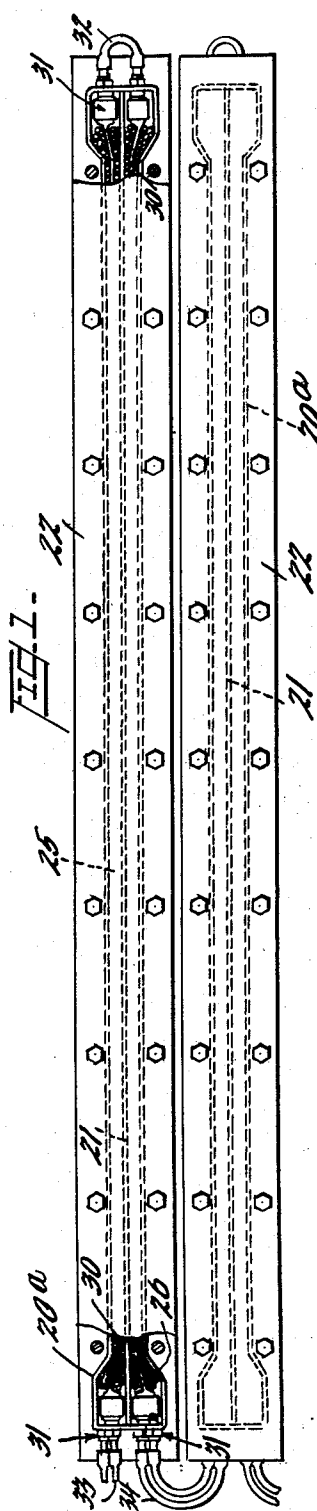
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2,683,117

DIALYZERS

Filed April 10, 1950

4 Sheets-Sheet 1



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DIALYZERS

Filed April 10, 1950

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FIG. 3-

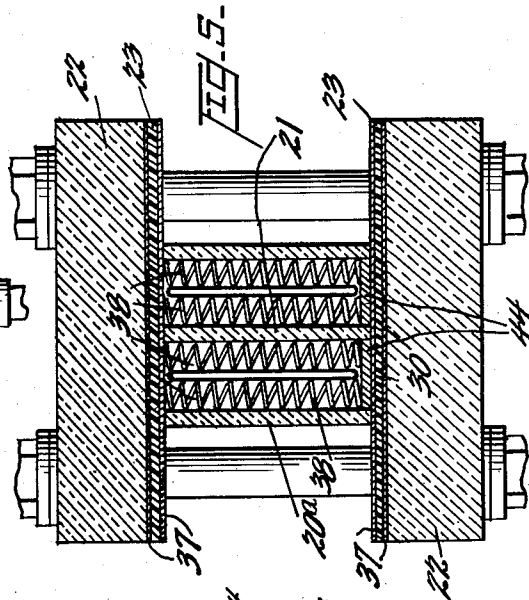
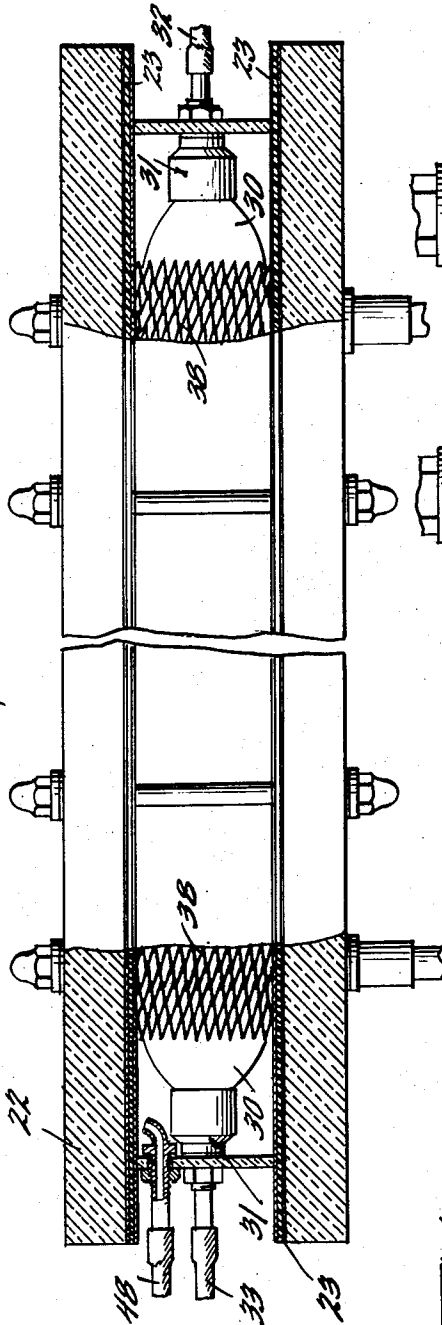
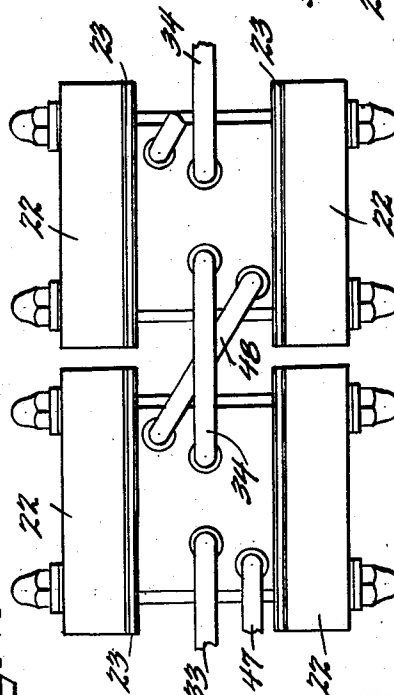


FIG. 4-



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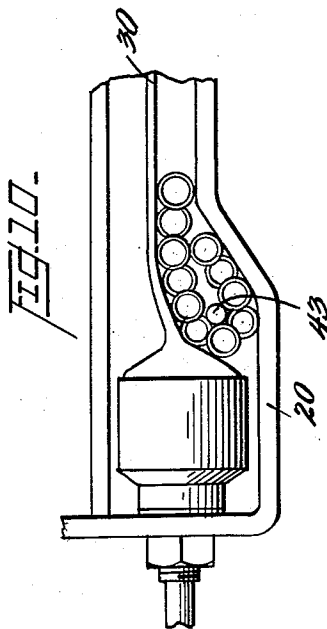
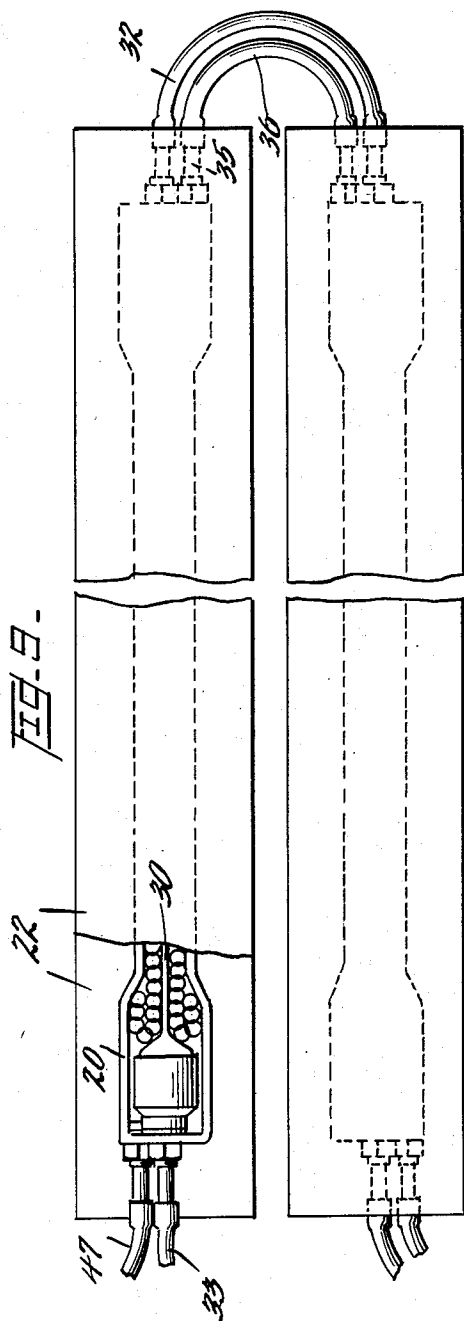
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2,683,117

DIALYZERS

Filed April 10, 1950

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2,683,117

DIALYZERS

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Application April 10, 1950, Serial No. 155,054

6 Claims. (Cl. 210—8.5)

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This invention relates to dialyzers and particularly to dialyzers designed and constructed in such manner as to be particularly useful in conditioning human blood.

The phenomena of dialysis is well known, and it has been recognized heretofore that human blood may be conditioned by subjecting it to dialytic action under certain conditions which are so controlled as to bring about an exchange of factors between a wash medium and the blood being conditioned, which exchange results in the introduction into the blood stream of a patient factors which compensate for blood deficiencies, and the removal therefrom of deleterious factors which have been caused by disease, particularly by disease of the kidneys.

The general purpose of this invention is to provide a dialyzer which comprises a plurality of interchangeable and easily replaceable units, any one of which may be by-passed or replaced without discontinuing the operation of the dialyzer.

A further object of the invention is to provide an extra corporeal blood dialyzer having a series of interchangeable units each of which comprises a frame which aids in supporting a straight septum, and which is provided with connections between septa of adjacent units externally of the frames. The external connections permit a suitable pump to be inserted into the channel defined principally by the septa to assist in propelling through the dialyzer the blood which is to be conditioned when the heart condition of the patient appears to require such precautionary assistance.

A further object is to provide a blood dialyzer of improved efficiency and safety which comprises a plurality of units each of which has a straight septum which is supported free of wrinkling. A frame in which the septa are supported is provided with adapters communicating with the septum which smoothly conducts the blood flowing through the septa between the external connections referred to above and the various septa without trapping any portion of it. The adapters associated with each end of a septum are positioned on the frame so that the septum extends linearly between its associated adapters. Spacing screens arranged on either side of the septa, maintain the septa narrow in cross-section in order to cause dialyzing contact of the largest possible proportion of the blood passing through the dialyzer with the walls of the septa.

A further feature of the invention provides a

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dialyzer having a plurality of interchangeable units, each of which comprises a frame in which a septum is supported and each of which frames is provided with separate connections for introducing and discharging a wash medium in which the septum is to be immersed, whereby the potential of the wash medium with respect to the solution being treated may be altered at different points along the length of the interconnected septa. The construction employed also permits the wash medium to be introduced in parallel or in series into the several units, or partly in series and parallel as desired, thus also facilitating the maintenance of the wash medium at body temperature when blood is being dialyzed. Further, the septa may also be connected selectively in a manner which will cause the solution to be dialyzed to pass through the several septa of the dialyzer either in series or in parallel as desired.

A further object of the invention is to provide a dialyzer comprising a plurality of units each of which comprises a septum of relatively short length and which communicates at either end with adapters designed and constructed to readily permit assembly of the several units and which permit each of the septa to be readily pressure-tested prior to assembly of the dialyzer.

A further object of the invention is to provide a dialyzer comprising a plurality of units which units may be readily interconnected and replaced and which may be conveniently received in conventional sterilizing equipment such as a hospital autoclave and thereafter operably assembled without loss of sterility of the units; any looseness between parts of fittings caused by heating and cooling during sterilization may be taken up by making an external adjustment.

The invention also provides an extra-corporeal dialyzer which has a transparent housing for the frame of the unit which permits visual observation of the dialyzing process, and which is provided with a transparent sealing device between the housing and the frame of the dialyzer. The sealing device is faced with water-resistant transparent material which prevents the sealing device from becoming foggy or opaque during sterilization of the unit.

Other objects and advantages provided by the invention which promote the efficiency and safety with which blood may be conditioned by extra-corporeal dialysis will be apparent from the following detailed description made with reference to the accompanying drawings.

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In the drawings:

Figure 1 is a plan view illustrating two assemblies each of which comprise two dialyzer units constructed according to the instant invention, and illustrating the manner in which the assemblies are interconnected in setting up the dialyzer;

Figure 2 is a fragmentary view of two such interconnected assemblies illustrating the construction of the dialyzer units in more detail;

Figure 3 is a side view of a dialyzer unit, with a portion cut away to illustrate the relationship of the septum, the spacing screen, and the conduits for the wash solutions;

Figure 4 is an end view looking to the right in Figure 2;

Figure 5 is a transverse section taken along the line 5—5 of Figure 2;

Figure 6 illustrates an assembly comprising four dialyzer units;

Figure 7 illustrates a modified type of frame member and shows in detail an adapter which may be employed with either type of frame member, and which receives the septum and extends through the frame member for connection with the external connections between adjacent frame members;

Figure 8 is a transverse section along the line 8—8 of Figure 7;

Figure 9 is a plan view showing two basic dialyzer units constructed according to the instant invention, and the means by which such units are interconnected in assembling a dialyzer; a portion of one unit being cut away to reveal the details of construction of one end of the unit; and

Figure 10 is a fragmentary view of one end of a two unit assembly, such as shown in Figure 1, illustrating the arrangement of the screen grid and the grid post whereby the cross-sectional area of the septum proximate the adapter is minimized.

The basic dialyzer unit, two of which are shown interconnected in Figure 9, consists of a tubular septum positioned within a fluid tight housing which is arranged to provide a wash medium passage which envelops the septum. Each end of the septum is supported on an externally adjustable adapter through which the solution to be dialyzed is introduced into or discharged from the septum. The housing is also provided with intake and discharge ports at points proximate the ends of the wash medium passage, so that either the wash medium or the solution being dialyzed can selectively be passed in either direction through the unit. Several such units can be connected together in the manner illustrated in Figure 9 to provide a dialyzer of any desired capacity.

A dialyzer of this type may comprise a frame member 20 which is interposed between two transparent housing plates 22 which closely engage the opposite lateral edges of the frame member to form a fluid tight chamber or chambers. The flattened tubular septum 30 is supported in this chamber, and the septa of adjacent units are adapted for interconnection by conduit 32 positioned externally of the unit. The wash medium passages (defined between the septum and the housing consisting of the frame and housing plates) of adjacent units are also provided with means which adapt them for interconnection.

The blood which is to be conditioned is introduced into the septum through a conduit 33 com-

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municating therewith, and the wash medium is introduced through conduit 47 communicating with the wash medium passage and caused to flow through the passage in contact with the outer surface of the septum to establish the conditions necessary for the osmotic exchange of crystalloids through the septum. An outlet conduit 35 for the wash medium is supported in the end wall of the frame member. The arrangement is such that the outlet conduit of one such unit may be connected to a similar conduit in an adjacent unit by means of a conduit such as 36 positioned externally of the frame member, whereby a dialyzer of any desired size may be assembled.

For greater convenience in handling and assembling a dialyzer, two or more basic dialyzer units may be formed into an assembly which employs the same housing plates for the several assembled units. An assembly consisting of two basic units is illustrated most clearly in Figure 2, and an assembly consisting of four basic units is shown in Figure 6. In both constructions of this type the frame member 20a comprises an endless strip of metal generally rectangular in cross-section and having its lateral edges lying in parallel planes. The central portion of the elongated sides of the frame member lie parallel to one another and diverge slightly at either end to form enlarged end portions in which the adapters which communicate with the tubular septum are conveniently received.

Each such frame member is provided with a longitudinally disposed partition 21 extending the length of the frame and secured to the end walls midway between the side walls thereof. The partition is of the same height as the walls of the frame member and divides the frame member into separate wash medium passages or dialyzing chambers 25 and 26 when the frame member is interposed between the transparent housing plates 22. An alternative construction of the frame member and partition is shown in Figure 7. As there shown, the frame member 20b may have rectilinear sides, and the enlarged cavities at either end which accommodate the septa connecting adapters may be provided by reducing the width of the end portions of the central partition 21a. Preferably, the single assembly should not consist of more than two such frames as shown in Figure 6 as otherwise the regulation of the septum length of the complete dialyzer cannot be obtained with the desired accuracy. Furthermore, a failure in one septum of a larger unit will require immobilizing too great a proportion of the total septum length.

In each type of construction, a seal 23, seen most clearly in Figure 5, may be interposed between the edges of the frame member and the proximal surfaces of the upper and lower housing plates 22 which plates are preferably made of transparent material. The seal 23 is preferably a transparent plastic material such as Vinylite, or a similar transparent artificial resin, having sufficient softness to yield slightly at the points at which the seal is contacted by the lateral edges of the frame. The edges of the frame and partition thus rest in a slight groove thereby insuring a firm, liquid tight contact between the edges of the frame, the partition and the seal.

It has been found that discoloration and fogging of the resin seal which occurs when the seal is exposed to the heat and moisture encountered during sterilization of the dialyzer may be avoid-

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ed by covering each side of the seal with a sheet of water-resistant transparent material 37. The seal thus protected by a sheet of transparent fluid-resistant material is shown in assembled position in Figures 5 and 8.

In the type of construction illustrated most clearly in Figures 2 and 6, the two dialyzing chambers 25 and 26 defined between the walls of the frame member 20a and the housing plates 22 communicate with each other through an aperture 24 provided in the partition adjacent the end wall opposite from the end wall through which the wash medium is introduced into the chamber 25.

Septa 30 are disposed lengthwise within each of the chambers 25 and 26 and communicate at either end with adapters indicated generally at 31. The adapters extend through the end walls of the frame as seen most clearly in Figure 2. A conduit 32 communicates between the adapters 31 in the frame wall adjacent the apertures 24 and serves to conduct the solution passing from the septum in the chamber 25 into the septum disposed in the chamber 26. The adapters 31 in the other end wall of the frame member are provided with connecting means such as 33 which may be employed to introduce the solution into the septum of the dialyzer, and connecting means such as 34 which transfer the solution discharged from the septum of one unit into the septum of an interconnected unit as illustrated in Figures 2 and 6.

Preferably, septum 30 comprises a seamless cellophane tube which in the dialyzer illustrated is required to be of relatively short length, and accordingly may be obtained conveniently without undesirable minute perforations, or "pin-holes" which are frequently found in such seamless cellophane tubes of substantially greater length.

In addition to the support supplied to the ends of the flattened tubular septa by the adapters 31, support is provided by the screen grids 38 which are interposed between the central portion of the longitudinal walls of each chamber and the septa as illustrated most clearly in Figures 2, 5, 7 and 8. The screen grids 38 are comprised of interwoven spiraled wire which may be either a single spiral or a rigid spiral weave and serve to support the central portion of the septum in the flat condition which presents the greatest dialyzing area per volume of solution contained within the tubular septum. The screen grids also prevent the pressure exerted by the fluid within the septum from expanding the septum and interfering with the flow of wash medium through the dialyzing chambers.

The screen grids on either side of the septum are made long enough so that they may be doubled back on themselves for a short distance. The spaces between the grids in the enlarged portions of the chambers are thus reduced, and the ends of the septa are maintained in flattened condition up to a point immediately adjacent the heads of the adapters 31. A preferable means for maintaining the end portions of the septa in flattened condition is illustrated in Figure 10. This construction comprises a vertically disposed post 43 which may be inserted in the turn of the doubled back portion of the grids in order to obtain a further reduction of the space between the grids supporting the ends of the septa. It will be apparent that the cross-sectional area of the ends of the septa may be varied as desired by inserting posts of different cross-sectional areas

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or coiling the ends of the screen grid about the posts to different extents.

Further provisions are made to establish and maintain the desired cross-sectional area of the septa. A series of spacing plates 44 of relatively short length are positioned apart from one another between the inner lower edges of the frame members as shown most clearly in Figures 2 and 5. The parallel portions of the side walls of the frame members are thus retained apart the distance which will properly space the screen grids. In turn, the spacing of the screen grids determines the cross-sectional area of the interposed septa. The walls of the frame members may be retained against displacement away from one another by means of lugs or similar stops supported on the housing plates. In a four unit assembly, such as that illustrated in Figure 6, spacers such as 44a, shown in dotted lines, may be placed between the mutually facing sides of adjacent frame members.

In addition to maintaining the septa in the efficient flattened condition, the septa supporting means described above are effective to maintain the septa clear of both the top and bottom housing plates so that the wash medium introduced into the dialyzing chambers contacts the entire outer surface of the septa. Accordingly, the maximum dialyzing action is obtained.

The adapters 31 which receive the septum disposed in the dialyzing chambers 25 and 26, respectively, are designed to support the septum in a manner which prevents the solution being passed through the septum from being hindered or trapped at any point during its passage through the dialyzing channel provided by the interconnected septa. This factor is especially important when the dialyzer is being employed to condition blood.

As shown most clearly in Figure 7, it will be seen that the adapter 31 comprises a sleeve portion 39. One end of the annular sleeve 39 has an enlarged end provided with a central bore which tapers inwardly towards the central longitudinal axis of the sleeve. The other end of the sleeve is provided with an annular shoulder which rests against the inner side of the end wall of the frame, and the annular portion 39(b) which depends from the shoulder is received in an aperture provided in the end wall of the frame. A fitting 40 extends through the sleeve 39 and is provided with a conical end portion 40(a), the outer surface of which acts as a wedging surface in conjunction with the tapered surface 39(a). The end portion of the septa 30 envelopes the conical portion 40(a) of the fitting and is thus interposed between the wedging surfaces. Thus, it may be firmly secured between the wedging surfaces by drawing the fitting 40 into the sleeve 39 by means of the tightening nut 41 which threadably engages the portion of the fitting 40 which extends through the end wall. Accordingly, an adapter thus constructed provides a means for effecting a smooth and unimpeded flow of the solution passing through the interconnected septa of the dialyzer during the portions of the passage where the solution flow is being reversed in direction.

The most important advantage of this construction, however, is that the fluid tight connection between the septa and the fitting may be repaired by adjustment of the nut 41 without disassembling the unit and without touching any parts thereof with which the solution to be dialyzed will contact. In blood dialyzers, for ex-

ample, it is imperative to maintain the dialyzer in a sterile condition. This sterility is obtained generally by treating the unit in an autoclave. The heating and cooling to which the unit is thus subjected frequently causes unequal changes in the sizes of parts of the fittings. This results in sealing engagements between parts of the adapters being destroyed. The described construction of the adapters 31 permit the sealing engagement between the septa and the adapters to be re-established after sterilization of the unit by external adjustment, whereby the sterility of all the internal parts may be conserved.

An important feature of the invention is providing the means for interconnecting the septa of adjacent dialyzing compartments externally of the frame which, in part, defines the compartments. This construction permits ready interchange of units of the dialyzer during the operation thereof without polluting the sterility of the remaining units being employed and permits the dialyzing process to be continued without substantial alteration even though one of the units of the complete dialyzer becomes inoperative. The external connection between units also makes it possible to insert a specially designed pumping means into the dialyzing channel comprising the septa where the dialyzer is being utilized as an extra corporeal blood dialyzer and the patient's heart is not capable of propelling blood through the dialyzer. Constructing the dialyzer as a plurality of units each of which comprises a septum communicating with external connections for interconnecting the units also facilitates testing the seamless septa for imperfections by applying suitable testing pressure, and thus quickly localizing defects in the septa. Fitting 42 (Figure 2) is provided for the purpose of receiving a manometer used to indicate the pressure of the wash medium, or to receive a thermometer for measuring the temperature of the wash medium.

The sleeve and fittings may be formed from glass, stainless steel, or similar material having hard, bright, non-reactive surfaces which are easily cleaned and sterilized. Polyamide resins, such as nylon, have been found to meet the requirements.

One end of each of the frames 20a is provided with conduits for admitting and discharging the wash medium. The conduits are positioned to either side of the central partition so that the wash medium is caused to flow around the tubular septum for the length of compartment 25, through the passage 24 provided in the partition, and along the length of the septum in the adjacent dialyzing compartment 26 to the discharge conduit. The dialyzing chambers may be connected to a source of wash medium by means of a conduit 47 communicating with the fitting 46, and the wash medium may be passed serially through the several units of the dialyzer by means of an interconnecting conduit 48 connected to the wash medium discharge fitting 46 of one unit and to the wash medium inlet fitting 46 of the adjacent unit as illustrated in Figures 2, 4 and 6.

It will be apparent that the arrangement by which the wash medium is transferred from one unit of the dialyzer to the adjacent unit, or fed from the wash medium source directly to each unit, by connecting means positioned externally of the frame or the housing of the dialyzer, facilitates accurate control of the temperature of the wash medium and of the solution contained with-

in the septum which is immersed in the wash medium. Further, the potential of the wash medium, which is dependent on the relative concentration of a particular crystalloid in the solutions on either side of the septum, may be widely varied as desired. For example, the wash medium may be caused to flow in the same direction as the solution, or in the opposite direction, or in any desired combination of both depending upon the requirements of the particular case. It is also possible, due to the external connections for the wash medium for each unit, to utilize different wash mediums in each of the separate units. Further variations in the potential of the wash medium may be obtained by serially connecting the several dialyzing chambers to the source of wash medium, or by directly connecting each of the several units to the source of wash medium.

It will be apparent from the foregoing description that the instant dialyzer is particularly suitable for conditioning human blood by dialytic action due to the manner in which the process may be finely controlled and defective units of the dialyzer readily replaced during operation thereof.

Having thus described the invention, what is new and desired to be secured by Letters Patent is:

1. In a dialyzer, in combination, an elongated channel having an aperture in an end wall thereof, an elongated tubular septum disposed within said channel, a clamping assembly for releasably supporting the end of the septum in desired position within the channel, said assembly including a member having a portion disposed within the septum at one end thereof, a second member encircling said first member and the interposed end portion of the septum, said members being relatively movable to clamp or release the intermediate septum as desired, and one such member having a portion projecting through said aperture in the channel wall to the exterior of said channel, and means associated with the projecting portion of said member, and located without the channel, for relatively moving said members to clamp said septum or release the same as desired.

2. In a dialyzer, in combination, an elongated channel having an aperture in an end wall thereof, an elongated tubular septum disposed within said channel, a clamping assembly for releasably supporting the end of the septum in desired position within the channel, said assembly including a member having a portion disposed within the septum at one end thereof, a second member encircling said first member and the interposed end portion of the septum, said members being relatively movable axially to clamp or release the intermediate septum as desired, and one such member having a portion projecting through said aperture in the channel wall to the exterior of said channel, and means associated with the projecting portion of said member, and located without the channel, for relatively moving said members axially to clamp said septum or release the same as desired.

3. The combination set forth in claim 2 in which said second member is movable relatively to said channel and is drawn into liquid-tight engagement therewith when said members are moved into clamping engagement with said septum.

4. The combination set forth in claim 2 in which said second member encircles the aperture in said channel and is drawn into sealing

engagement with the wall of said channel when said members are moved into clamping engagement with said septum.

5. The combination set forth in claim 2 in which said projecting portion is integral with said first member and said first member and projecting portion constitute a tubular prolongation of the septum.

6. A dialyzer comprising a plurality of adjacent elongated rectangular frames, an adapter extending through the end walls of each of said frames, a tubular septa supported within each of said frames, each end of said septa being directly connected to one of said adapters, connecting means removably engaging the adapters on adjacent frames externally of said frames, whereby a single channel of desired length may be provided for a solution to be dialyzed, a spacing screen disposed between each side of the respective septa and the adjacent side wall of said frames thereby supporting said septa out of contact with said frame on all sides, said septa being linearly disposed between the conduits at either end of the respective frames, said adapt-

ers comprising an annular sleeve in register with an aperture provided in each of the end walls of the respective frames, the bore of the distal end of said sleeve being tapered to provide a wedging surface, a tube extending through said sleeve and having an enlarged smooth bored end portion providing a second wedging surface, and one end of the septum enveloping the said enlarged portion and being clamped between the two said wedging surfaces.

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